APR 2 0 2004

Section 4
510(K) Summary
CoolTouch® Nd:YAG Laser Systems

K 040131

Applicant:	New Star Lasers, Inc.
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson
Telephone / Fax / Email	916-677-1912 – Phone 916-677-1901 – Fax
Preparation Date:	January 14, 2004
Device Trade Name:	CoolTouch® Nd:YAG Laser System CoolTouch® II Nd:YAG Laser System CoolTouch® CT3 Nd:YAG Laser System
Common Name:	Nd:YAG Pulsed Surgical Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-4810
Legally Marketed Predicate Device:	Candela Smoothbeam™ Laser System K030834 Treatment of mild to moderate inflammatory acne vulgaris.
Description of the CoolTouch® Nd:YAG Laser Systems	The CoolTouch® Nd:YAG Laser Systems are ND:YAG lasers producing laser emission at 1320nm. The lasers consist of three interconnected section: a) The cabinet, which houses the power supply, cooling system , microcontroler and the laser, b) the fiber optics and c) the handpiece.
Intended use of the CoolTouch® Nd:YAG Laser Systems	The CooTouch® Nd:YAG Laser System are indicated for the treatment of mild to moderate inflammatory acne vulgaris.
Performance Data:	None
Conclusion:	The CoolTouch® Nd:YAG Laser System is substantially equivalent to other existing laser systems in commercial distribution for treatment of mild to moderate inflammatory acne vulgaris.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2004

Mr. Donald V. Johnson
Vice President, Operations
New Star Lasers, Inc.
9085 Foothills Boulevard
Roseville, California 95747

Re: K040131
Trade/Device Name: CoolTouch® Nd:YAG Laser System, CoolTouch® II Nd:YAG Laser System, CoolTouch® CT3 Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 16, 2004
Received: January 21, 2004

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K 040131

Device Name: CoolTouch®, CoolTouch® II, and CoolTouch® CT3 ND:YAG Laser Systems

Indications for Use:

The CoolTouch®, CoolTouch® II, and CoolTouch® CT3 ND:YAG Laser Systems are indicated for the treatment of mild to moderate inflammatory acne vulgaris.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040131

Prescription Use ✓ OR Over-the-Counter Use____
(per 21 CFR 801.109)